



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,842	10/26/2001	Michel J.N. Cormier	ARC 3036 R1	2394

22921 7590 11/02/2005

ALZA CORPORATION
P O BOX 7210
INTELLECTUAL PROPERTY DEPARTMENT
MOUNTAIN VIEW, CA 940397210

EXAMINER

MICHENER, JENNIFER KOLB

ART UNIT	PAPER NUMBER
----------	--------------

1762

DATE MAILED: 11/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/045,842

Applicant(s)

CORMIER ET AL.

Examiner

Jennifer K. Michener

Art Unit

1762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24, 28-35 and 38-50 is/are pending in the application.
- 4a) Of the above claim(s) 1-17, 38-46 and 48-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-24, 28-35 and 47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/3/04; 10/21/02</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Newly submitted claims 49 and 50 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: like spray-coating, the inventions of claim 49 and 50, respectively directed to microfluid deposition and inkjet printing, are independent from the dipping invention of claim 47.

Accordingly, claims 49 and 50 are withdrawn from consideration, along with the spray-coating claim 48, as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 18-24, 28-35, and 47 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 54-64 of copending Application No. 11/034,891. Although the conflicting claims

are not identical, they are not patentably distinct from each other because the Application teaches the limitations of the claims and only fails to teach the dose, solubility, and viscosity of the agent of the instant claims. However, claims in the 11/034,891 application are directed to the same active agents as the claims and specification of the instant application, which would inherently be useful in the same dosage, solubility, and viscosity as instantly claimed.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 21, 23, and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 21, the phrase "said coating being less than a thickness of the microprotrusions" is confusing. Less what? Perhaps Applicant intends to state that the coating is less thick than the microprotrusion is thick?

In claim 23, the language is confusing. The hormones, such as "LHRH" must be spelled out. Additionally, the terms in parentheses and brackets (such as "(1-24)" and "[Val4, D-Arg8]") render the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention.

In claim 29, Applicant claims different therapeutically effective amounts.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

7. Claims 18-22, 28-33, and 47 are rejected under 35 U.S.C. 102(e) as being anticipated by Dalton (WO 02/07813).

Dalton teaches a method of making a device for transdermally delivering a pharmacologically active agent by providing a member with a plurality of stratum-corneum-piercing microprotrusions, applying an aqueous solution of the agent (p. 12, line 9) onto the member, and drying to form a dry coating on the member.

Art Unit: 1762

Dalton teaches that any agent may be used, but provides insulin as an exemplary agent (p. 4, line 19). Examiner asserts that insulin is therapeutically effective when administered in a dose of less than about 1 mg and that an aqueous solution of insulin has the solubility and viscosity claimed. Additionally, Dalton teaches loading with agent in the nanogram or microgram range (p. 13, line 4), which is inherently an effective dose meeting the claims.

Specifically, Dalton teaches coating the microprotrusions on the member, as required by various claims (abstract and throughout).

The range of lengths for the microprotrusions of Dalton lies within the range claimed (p. 6, line 4).

The thickness of the coating in Dalton appears to be "less" thick than the microprotrusions, which meets claim 21, depending on clarification of the 112 issue.

Additionally, due to the length of the microprotrusions and based on the drawings, the thickness of coating must be less than that claimed in claims 31-32.

Dalton teaches application in a pattern. Since only the microprotrusions are coated, the pattern is not contiguous.

Dalton teaches dipping (Examples).

Dalton teaches the use of an adjuvant (p. 4, line 29).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1762

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 23-24 and 34-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dalton.

Dalton teaches that which is disclosed above, but fails to teach the density of loading of the agent. Examiner notes that density of loading directly impacts the dose administered. It would have been within the skill of an ordinary artisan to carefully select a dose, and thus the loading, of a therapeutic agent to achieve a desired result in a patient.

It is well settled that determination of optimum values of cause effective variables such as these process parameters is within the skill of one practicing in the art. *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Regarding claims 23-24, the only therapeutic hormone example provided by Dalton is insulin and he fails to specifically teach the use of glucagon or desmopressin. Examiner notes, however, that insulin is a hormone, namely a protein, produced in the pancreatic islets, that provides a counter hormone to glucagon. Additionally, Dalton teaches that any therapeutic agent is useful in his invention. It would have been obvious to one of ordinary skill in the art to use another hormone that regulates urination or digestive function (such as insulin) on a transdermal system of microprotrusions as provided by Dalton with the expectation of successful dosing results.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Beaumont et al. is cited for teaching the inherency relied upon above that insulin (taught by Dalton) as well as glucagon or calcitonin (claimed by Applicant) are effective at doses less than 1 mg.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer K. Michener whose telephone number is (571) 272-1424. The examiner can normally be reached on Mondays & on Tuesday and Wednesday afternoons.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy H. Meeks can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1762

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'J. Michener', with a stylized flourish at the end.

Jennifer Michener
Primary Examiner
Art Unit 1762
October 31, 2005